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All Active Events – EphMRA ATC Code – J5B1 (Viral Hepatitis Products)

13 May 2015

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All Financial Data in US $ (mln)

	Event Type	Product	Company	Product NPV	Product NPV as % Mkt Cap	Event	Event Status	Start Date	End Date
J (General Anti-Infectives Systemic)									
J5 (Antivirals for Systemic Use)									
J5B (Antivirals, Excl. Anti-HIV Products)									
J5B1 (Viral Hepatitis Products)	Phase III Trial Initiation	Sovaprevir	Achillion Pharmaceuticals	1,868	165%	Phase III Trial Initiation for Sovaprevir for HCV Infection[1]	Overdue by 133 days	01 Oct 2014	31 Dec 2014
	Phase II Trial Initiation			1,868	165%	Phase II Trial Initiation for ACH-3102 and Sovaprevir for HCV Infection[2]	In-Play (58%)	06 Mar 2015	30 Jun 2015
	Phase II Trial Initiation			1,868	165%	Phase II Trial Initiation for ACH-3422, ACH-3102 and Sovaprevir for HCV Infection[3]	Starts in 141 days	01 Oct 2015	31 Dec 2015
	Phase II Trial Initiation	ACH-3102	Achillion Pharmaceuticals	-	-	Phase II Trial Initiation for ACH-3102 and ACH-3422 for HCV Infection[4]	In-Play (58%)	06 Mar 2015	30 Jun 2015
	Phase II Trial Initiation			-	-	Phase II Trial Initiation for ACH-3102 and Sovaprevir for HCV Infection[5]	In-Play (58%)	06 Mar 2015	30 Jun 2015
	Phase II Trial Initiation			-	-	Phase II Trial Initiation for ACH-3422, ACH-3102 and Sovaprevir for HCV Infection[6]	Starts in 141 days	01 Oct 2015	31 Dec 2015
	Phase II Trial Initiation	ACH-3422	Achillion Pharmaceuticals	-	-	Phase II Trial Initiation for ACH-3102 and ACH-3422 for HCV Infection[7]	In-Play (58%)	06 Mar 2015	30 Jun 2015
	Phase II Trial Initiation			-	-	Phase II Trial Initiation for ACH-3422, ACH-3102 and Sovaprevir for HCV Infection[8]	Starts in 141 days	01 Oct 2015	31 Dec 2015
	US Product Filing	RG7227	Array BioPharma	-	-	Expect US Filing for Danoprevir for Hepatitis C[9]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	EU Product Filing			-	-	Expect EU Filing for Danoprevir for Hepatitis C[10]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	Phase II Trial Results	ABT-493	Enanta Pharmaceuticals	416	61%	Phase IIb Trial Results for ABT-493 in combination with ABT-530 for Hepatitis C treatment[11]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	Phase III Trial Initiation			416	61%	Phase III Trial Initiation for ABT-493 in combination with ABT-530 for Hepatitis C treatment[12]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	US Product Approval (PDUFA)	Viekirax	Enanta Pharmaceuticals	-	-	FDA Decision Date (PDUFA) on Ombitasvir/Paritaprevir/Ritonavir for Chronic genotype 4 hepatitis C virus infection[13]	Starts in 141 days	01 Oct 2015	01 Oct 2015
	Japan Product Approval			-	-	Japanese Regulatory Decision on Ombitasvir/Paritaprevir/Ritonavir for Chronic genotype 1 hepatitis C virus infection[14]	Starts in 49 days	01 Jul 2015	31 Dec 2015
	US Product Approval (PDUFA) - 2nd Review	Daklinza	Bristol-Myers Squibb	2,163	2%	FDA Decision Date (PDUFA) on Daklinza for Hepatitis C Genotype 3[15]	Starts in 121 days	11 Sep 2015	11 Sep 2015

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	Event Type	Product	Company	Product NPV	Product NPV as % Mkt Cap	Event	Event Status	Start Date	End Date
	US Product Filing	Daclatasvir/Asunaprevir/Beclabuvir	Bristol-Myers Squibb	-	-	Expect US Filing for Daclastavir/Asunaprevir/Beclabuvir for hepatitis C[16]	Overdue by 43 days	01 Jan 2015	31 Mar 2015
	Phase III Trial Results	Incivek	Eli Lilly	-	-	Phase III Trial Results for Incivek for People Co-infected with HCV and HIV[17]	Starts in 19 days	01 Jun 2015	30 Jun 2015
	US Product Filing	RG7227	Gilead Sciences	-	-	Expect US Filing for Danoprevir for Hepatitis C[18]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	EU Product Filing			-	-	Expect EU Filing for Danoprevir for Hepatitis C[19]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	Japan Product Approval	Harvoni	Gilead Sciences	29,168	19%	Japanese Regulatory Decision on Harvoni for Chronic Hepatitis C Infection[20]	Starts in 141 days	01 Oct 2015	31 Mar 2016
	Phase III Trial Results	Sofosbuvir/ GS-5816	Gilead Sciences	332	0%	Phase III Trial Results for Sofosbuvir/ GS-5816 for Hepatitis C treatment[21]	Starts in 49 days	01 Jul 2015	31 Dec 2015
	Phase III Trial Results	Incivo	Johnson & Johnson	5	0%	Phase III Trial Results for Incivek for People Co-infected with HCV and HIV[22]	Starts in 19 days	01 Jun 2015	30 Jun 2015
	Phase III Trial Initiation	MK-5172	Merck & Co	-	-	Phase III Trial Initiation for Grazoprevir and MK-3682 for Hepatitis C treatment[23]	In-Play (29%)	05 Feb 2015	31 Dec 2015
	Phase III Trial Initiation	MK-8742	Merck & Co	-	-	Phase III Trial Initiation for Grazoprevir and MK-3682 for Hepatitis C treatment[24]	In-Play (29%)	05 Feb 2015	31 Dec 2015
	Phase III Trial Initiation	MK-8408	Merck & Co	-	-	Phase III Trial Initiation for Grazoprevir and MK-3682 for Hepatitis C treatment[25]	In-Play (29%)	05 Feb 2015	31 Dec 2015
	US Product Filing	Grazoprevir/Elbasvir	Merck & Co	5,193	3%	Expect US Filing for Grazoprevir/Elbasvir for Hepatitis C[26]	In-Play (28%)	25 Apr 2015	30 Jun 2015
	Phase III Trial Results			5,193	3%	Phase III Trial Results for Grazoprevir/Elbasvir for Hepatitis C[27]	In-Play (28%)	25 Apr 2015	30 Jun 2015
	Phase III Trial Results	Sofosbuvir/ GS-5816	Mylan	-	-	Phase III Trial Results for Sofosbuvir/ GS-5816 for Hepatitis C treatment[28]	Starts in 49 days	01 Jul 2015	31 Dec 2015
	US Product Filing	RG7227	Roche	30	0%	Expect US Filing for Danoprevir for Hepatitis C[29]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	EU Product Filing			30	0%	Expect EU Filing for Danoprevir for Hepatitis C[30]	Starts in 233 days	01 Jan 2016	31 Dec 2016
	Phase II Trial Results	RG7790	Roche	-	-	Phase IIb Trial Results for RG7790 for Hepatitis C[31]	Overdue by 133 days	17 Oct 2014	31 Dec 2014
	Phase III Trial Results	Incivek	Vertex Pharmaceuticals	31	0%	Phase III Trial Results for Incivek for People Co-infected with HCV and HIV[32]	Starts in 19 days	01 Jun 2015	30 Jun 2015
	Phase II Trial Results	Miravirsen	GlaxoSmithKline	-	-	Phase II Trial Results for SPC3649 for Hepatitis C treatment[33]	Overdue by 102 days	01 Jan 2015	31 Jan 2015

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All Financial Data in US $ (mln)

	Event Type	Product	Company	Product NPV	Product NPV as % Mkt Cap	Event	Event Status	Start Date	End Date
	Phase II Trial Initiation	RG-101	GlaxoSmithKline	-	-	Phase II Trial Initiation for RG-101 for Hepatitis C treatment[34]	In-Play (47%)	01 Apr 2015	30 Jun 2015
	Phase II Trial Results	OBP-701/ TT-033/ PF-05095808	Pfizer	-	-	Phase I/IIa Trial Results for TT-034 for Hepatitis C treatment[35]	Starts in 111 days	01 Sep 2015	30 Sep 2015
	Phase II Trial Initiation	RG-101	Isis Pharmaceuticals	-	-	Phase II Trial Initiation for RG-101 for Hepatitis C treatment[36]	In-Play (47%)	01 Apr 2015	30 Jun 2015
	Phase II Trial Initiation	RG-101	Alnylam Pharmaceuticals	-	-	Phase II Trial Initiation for RG-101 for Hepatitis C treatment[37]	In-Play (47%)	01 Apr 2015	30 Jun 2015
	Phase II Trial Results	OBP-701/ TT-033/ PF-05095808	Benitec	-	-	Phase I/IIa Trial Results for TT-034 for Hepatitis C treatment[38]	Starts in 111 days	01 Sep 2015	30 Sep 2015
	Phase II Trial Results	Miravirsen	Santaris Pharma	-	-	Phase II Trial Results for SPC3649 for Hepatitis C treatment[39]	Overdue by 102 days	01 Jan 2015	31 Jan 2015
	Phase II Trial Initiation	RG-101	Regulus Therapeutics	3,626	533%	Phase II Trial Initiation for RG-101 for Hepatitis C treatment[40]	In-Play (47%)	01 Apr 2015	30 Jun 2015
	Phase III Trial Results	Ropeginterferon Alfa 2b	PharmaEssentia	-	-	Phase III Trial Results for AOP2014/ P1101 for Polycythaemia vera[41]	Starts in 111 days	01 Sep 2015	30 Sep 2015
	Phase II Trial Initiation	RG-101	Stanford University	-	-	Phase II Trial Initiation for RG-101 for Hepatitis C treatment[42]	In-Play (47%)	01 Apr 2015	30 Jun 2015
	Phase II Trial Results	ABT-493	AbbVie	-	-	Phase IIb Trial Results for ABT-493 in combination with ABT-530 for Hepatitis C treatment[43]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	Phase III Trial Initiation			-	-	Phase III Trial Initiation for ABT-493 in combination with ABT-530 for Hepatitis C treatment[44]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	Phase II Trial Results	ABT-530	AbbVie	-	-	Phase IIb Trial Results for ABT-493 in combination with ABT-530 for Hepatitis C treatment[45]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	Phase III Trial Initiation			-	-	Phase III Trial Initiation for ABT-493 in combination with ABT-530 for Hepatitis C treatment[46]	In-Play (36%)	01 Jan 2015	31 Dec 2015
	US Product Approval (PDUFA)	Viekirax	AbbVie	-	-	FDA Decision Date (PDUFA) on Ombitasvir/Paritaprevir/Ritonavir for Chronic genotype 4 hepatitis C virus infection[47]	Starts in 141 days	01 Oct 2015	01 Oct 2015
	Japan Product Approval			-	-	Japanese Regulatory Decision on Ombitasvir/Paritaprevir/Ritonavir for Chronic genotype 1 hepatitis C virus infection[48]	Starts in 49 days	01 Jul 2015	31 Dec 2015
	Phase III Trial Initiation	IDX21437	Merck & Co	-	-	Phase III Trial Initiation for Grazoprevir and MK-3682 for Hepatitis C treatment[49]	In-Play (29%)	05 Feb 2015	31 Dec 2015
	Phase II Trial Initiation	Samatasvir & IDX21437	Merck & Co	-	-	Phase II Trial Initiation for IDX21437 and samatasvir for Hepatitis C[50]	Overdue by 255 days	01 May 2014	31 Aug 2014

References

Source: Evaluate Ltd

Notes

1 Q4 2014: Expect Phase III trial initiation.

02 JUL 2013: Achillion Pharmaceuticals expects to initiate Phase III trials at the end of 2014. (Source: EP Vantage 02 JUL 2013).

2 H1 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015).

05 MAR 2015: Achillion Pharmaceuticals plans to initiate in the first half of 2015, Ithaca triplet regimen, a phase II trial evaluating ACH-3102 and sovaprevir with sofosbuvir for a treatment duration of 4 weeks. SVR4 results are expected in the second half of 2015.

3 Q4 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015).

05 MAR 2015: Achillion Pharmaceuticals expects to initiate by the end of 2015 a pharmacokinetic and viral kinetic study of ACH-3422, ACH-3102 and sovaprevir in patients with treatment-naïve genotype 1 HCV.

4 H1 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015).

05 MAR 2015: Company plans to initiate in the first half of 2015, Sparta Doublet Regimen for HCV, a Phase II trial with ACH-3422 in combination with ACH-3102 for patients with treatment-naïve genotype 1 HCV for treatment durations of 6, 8 and 12 weeks. SVR4 results are expected in the second half of 2015.

22 DEC 2014: Achillion Pharmaceuticals announced positive interim results from two studies supporting a short duration, potentially best-in-disease regimen of its proprietary NS5A and nucleotide inhibitors, ACH-3102 and ACH-3422.Company looks forward to initiating in 2015 short duration, pan-genotypic Phase 2 therapeutic trials to evaluate the doublet of ACH-3102 and ACH-3422.

04 NOV 2014: Achillion Pharmaceuticals disclosed in its third quarter 2014 results that it expects to report top-line results from ongoing Phase 1 trial of ACH-3422 later this quarter and looks forward to initiating a proprietary combination program evaluating ACH-3422, ACH-3102 and sovaprevir during 2015.

15 AUG 2014: Achillion Pharmaceuticals announced that company expects to report Phase 1 proof-of-concept results for ACH-3422 during the fall of this year, which will lead to the start of a Phase 2 combination program to evaluate company's proprietary doublet regimen (ACH-3102 and ACH-3422) for HCV that will begin before the end of 2014.

5 H1 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015).

05 MAR 2015: Achillion Pharmaceuticals plans to initiate in the first half of 2015, Ithaca triplet regimen, a phase II trial evaluating ACH-3102 and sovaprevir with sofosbuvir for a treatment duration of 4 weeks. SVR4 results are expected in the second half of 2015.

6 Q4 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015).

05 MAR 2015: Achillion Pharmaceuticals expects to initiate by the end of 2015 a pharmacokinetic and viral kinetic study of ACH-3422, ACH-3102 and sovaprevir in patients with treatment-naïve genotype 1 HCV.

7	H1 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015). 05 MAR 2015: Company plans to initiate in the first half of 2015, Sparta Doublet Regimen for HCV, a Phase II trial with ACH-3422 in combination with ACH-3102 for patients with treatment-naïve genotype 1 HCV for treatment durations of 6, 8 and 12 weeks. SVR4 results are expected in the second half of 2015. 22 DEC 2014: Achillion Pharmaceuticals announced positive interim results from two studies supporting a short duration, potentially best-in-disease regimen of its proprietary NS5A and nucleotide inhibitors, ACH-3102 and ACH-3422.Company looks forward to initiating in 2015 short duration, pan-genotypic Phase 2 therapeutic trials to evaluate the doublet of ACH-3102 and ACH-3422. 04 NOV 2014: Achillion Pharmaceuticals disclosed in its third quarter 2014 results that it expects to report top-line results from ongoing Phase 1 trial of ACH-3422 later this quarter and looks forward to initiating a proprietary combination program evaluating ACH-3422, ACH-3102 and sovaprevir during 2015. 15 AUG 2014: Achillion Pharmaceuticals announced that company expects to report Phase 1 proof-of-concept results for ACH-3422 during the fall of this year, which will lead to the start of a Phase 2 combination program to evaluate company's proprietary doublet regimen (ACH-3102 and ACH-3422) for HCV that will begin before the end of 2014.
8	Q4 2015: Expect Phase II trial initiation. Source: Achillion Pharmaceuticals Press Release (05 MAR 2015). 05 MAR 2015: Achillion Pharmaceuticals expects to initiate by the end of 2015 a pharmacokinetic and viral kinetic study of ACH-3422, ACH-3102 and sovaprevir in patients with treatment-naïve genotype 1 HCV.
9	2016: Expect US filing. Source: Roche Website (15 APR 2014). 15 APR 2014: Roche expects to file application for approval in US by 2016. 21 JUL 2011: Company expect US Filing for Danoprevir for Hepatitis C in 2014.
10	2016: Expect European filing. Source: Roche Website (15 APR 2014). 15 APR 2014: Roche expects to file application for approval in EU by 2016. 21 JUL 2011: Company expect EU Filing for Danoprevir for Hepatitis C in 2014.
11	2015: Expect Phase IIb trial results. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014). A Study to Evaluate the Safety and Antiviral Effect of Multiple Doses of ABT-493 and ABT-530 in Adults With Genotype 1 Hepatitis C Virus (HCV). ClinicalTrials.gov Identifier: NCT01995071 10 SEP 2014: Enanta Pharmaceuticals announced that AbbVie, Enanta's development partner for protease inhibitors for hepatitis C virus (HCV), has initiated a phase 2b clinical study with ABT-493, Enanta's next-generation protease inhibitor. The phase 2b study being conducted by AbbVie will evaluate the safety and efficacy of ABT-493 co-administered with ABT-530, AbbVie's next generation NS5A inhibitor, in HCV patients. AbbVie has informed Enanta that results from this trial are expected in 2015.
12	2015: Expect Phase III trial initiation. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014).

10 SEP 2014: AbbVie plans to start phase 3 development of ABT-493 in combination with ABT-530 next year.

13 Estimated PDUFA Date: 01 OCT 2015.

Review Type: 6 Months (Confirmed). Source: Enanta Pharmaceuticals Press Release (23 APR 2015).

23 APR 2015: Enanta Pharmaceuticals announced that AbbVie has stated that the U.S. FDA has accepted AbbVie's NDA and granted priority review for its all-oral, interferon-free, two direct-acting antiviral (2-DAA) treatment regimen consisting of the fixed-dose combination of ombitasvir, paritaprevir, ritonavir (OBV/PTV/r), with ribavirin (RBV) for the treatment of adult patients with chronic genotype 4 (GT4) hepatitis C virus (HCV) infection.

05 MAR 2015: AbbVie disclosed in its presentation that 2-DAA has been filed in U.S.

14 H2 2015: Expect Japanese regulatory decision. Source: Enanta Pharmaceuticals Press Release (12 FEB 2015).

16 APR 2015: AbbVie announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted priority review for its investigational, two direct-acting antiviral treatment of ombitasvir/paritaprevir/ritonavir. This all-oral treatment is interferon (IFN) and ribavirin (RBV)-free and will be dosed once daily.

12 FEB 2015: Enanta Pharmaceuticals announced that AbbVie has submitted an NDA to the Japanese Ministry of Health, Labour and Welfare (MHLW) seeking approval for AbbVie's investigational, once-daily dosed, all-oral, ribavirin (RBV)-free and interferon (IFN)-free, 12-week, two direct-acting antiviral treatment consisting of ombitasvir/paritaprevir/ritonavir (OBV/PTV/r). The submission is for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection. AbbVie has previously announced that they expect regulatory approval in Japan in the second half of 2015.

15 PDUFA Date: 11 SEP 2015. Source: Bristol-Myers Squibb Press Release (12 MAR 2015).

Review Type: 6 Months (Confirmed).

12 MAR 2015: Bristol-Myers Squibb announced that the resubmitted new drug application (NDA) for daclatasvir has been accepted for review by the U.S. Food and Drug Administration (FDA) for use in combination with sofosbuvir for the treatment of chronic hepatitis C (HCV) genotype 3. The original NDA has been amended to include data from the Phase III ALLY-3 trial, which showed high cure rates for the combination, with sustained virologic response 12 weeks after treatment (SVR12) in 90% of treatment-naïve and 86% of treatment-experienced genotype 3 HCV patients. SVR12 rates were higher (96%) in non-cirrhotic genotype 3 patients, regardless of treatment history. The FDA will now review the submission within a six-month timeframe.

16 Q1 2015: Expect US filing. Source: Bristol-Myers Squibb Press Release (07 APR 2014).

07 APR 2014: Bristol-Myers Squibb anticipates submitting daclatasvir/asunaprevir/BMS-791325 regimen for FDA review in Q1 2015.

17 JUN 2015: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (03 JAN 2012).

A Study to Treat Subjects With Telaprevir, Ribavirin, and Peginterferon Who Are Coinfected With HIV and Hepatitis C Virus (HCV). ClinicalTrials.gov Identifier: NCT01467479

08 JAN 2012: Phase 3 study in people co-infected with hepatitis C and HIV: Enrollment is ongoing in a Phase 3 trial of INCIVEK combination therapy in people co-infected with genotype 1 hepatitis C virus and HIV.

18 2016: Expect US filing. Source: Roche Website (15 APR 2014).

15 APR 2014: Roche expects to file application for approval in US by 2016.

21 JUL 2011: Company expect US Filing for Danoprevir for Hepatitis C in 2014.

19 2016: Expect European filing. Source: Roche Website (15 APR 2014).

15 APR 2014: Roche expects to file application for approval in EU by 2016.

21 JUL 2011: Company expect EU Filing for Danoprevir for Hepatitis C in 2014.

20 Q4 2015 - Q1 2016: Expect Japanese regulatory decision.

24 SEP 2014: Gilead Sciences announced that the company has submitted a New Drug Application (NDA) to Japan's Pharmaceutical and Medical Devices Agency (PMDA) for approval of an investigational once-daily fixed-dose combination of the NS5A inhibitor ledipasvir (LDV) 90 mg and the nucleotide analog polymerase inhibitor sofosbuvir (SOF) 400 mg for the treatment of chronic genotype 1 hepatitis C virus (HCV) infection in adults.

21 H2 2015: Expect Phase III trial results. Source: Mylan Press Release (26 JAN 2015).

Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks in Adults With Chronic HCV Infection (ASTRAL-1). ClinicalTrials.gov Identifier: NCT02201940

Comparison of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 12 Weeks in Adults With Chronic Genotype 2 HCV Infection (ASTRAL-2). ClinicalTrials.gov Identifier: NCT02220998

Comparison of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 24 Weeks in Adults With Chronic Genotype 3 HCV Infection (ASTRAL-3). ClinicalTrials.gov Identifier: NCT02201953

26 JAN 2015: Mylan disclosed that Phase 3 studies evaluating the combination of GS-5816 and sofosbuvir are currently underway, with data anticipated in the second half of 2015.

22 JUN 2015: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (03 JAN 2012).

A Study to Treat Subjects With Telaprevir, Ribavirin, and Peginterferon Who Are Coinfected With HIV and Hepatitis C Virus (HCV). ClinicalTrials.gov Identifier: NCT01467479

08 JAN 2012: Phase 3 study in people co-infected with hepatitis C and HIV: Enrollment is ongoing in a Phase 3 trial of INCIVEK combination therapy in people co-infected with genotype 1 hepatitis C virus and HIV.

23 2015: Expect Phase III trial initiation. Source: Merck & Co Interim Results (04 FEB 2015).

04 FEB 2015: Merck & Co disclosed that it has started the Phase 2 C-CRESTstudies to study combination regimens of grazoprevir and MK-3682 (formerly IDX21437) with either elbasvir or MK-8408 for the treatment of HCV infection. The company expects to begin Phase 3 studies in 2015.

24 2015: Expect Phase III trial initiation. Source: Merck & Co Interim Results (04 FEB 2015).

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25 2015: Expect Phase III trial initiation. Source: Merck & Co Interim Results (04 FEB 2015).

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26 H1 2015: Expect US filing. Source: Merck & Co Press Release (24 APR 2015).

24 APR 2015: Merck disclosed that it remains on track to submit the New Drug Application to U.S. FDA in first half of 2015.

08 APR 2015: Merck announced that grazoprevir/elbasvir has received two new Breakthrough Therapy designations from the U.S. FDA for the treatment of patients with chronic HCV genotype 4 (GT4) infection, and for the treatment of chronic HCV genotype 1 (GT1) infection in patients with end stage renal disease on hemodialysis. Company remains on track for NDA filing with the U.S. FDA during first half of 2015.

04 FEB 2015: Merck disclosed that on Jan. 30, 2015, the company received notification from the FDA of its intent to rescind Breakthrough Therapy Designation status for this combination treatment regimen, citing the availability of other recently approved treatments for Genotype 1 patients. The company expects to discuss this matter with the FDA and does not expect that it will impact its ability to file an NDA for this combination regimen or the timing of that filing.

12 JAN 2015: Merck expects to file a New Drug Application (NDA) with the FDA in the first half of 2015 for grazoprevir/elbasvir (MK-5172/MK-8742), the company's investigational oral, once-daily combination regimen for the treatment of chronic hepatitis C virus (HCV) infection.

11 NOV 2014: Merck plans to submit the New Drug Application for grazoprevir/elbasvir in 2015.

27 H1 2015: Expect Phase III trial results. Source: Merck & Co Press Release (11 NOV 2014).

Study of Efficacy and Safety of MK-5172 + MK-8742 With or Without Ribavirin for Participants With Hepatitis C Genotype 1, 4, 5, or 6 Infections Who Have Failed Prior Treatment With Pegylated Interferon + Ribavirin (MK-5172-068).

ClinicalTrials.gov Identifier: NCT02105701

Safety and Efficacy of MK-5172 + MK-8742 in Participants With Chronic Hepatitis C and Chronic Kidney Disease (MK-5172-052/C-SURFER). ClinicalTrials.gov Identifier: NCT02092350

An Efficacy and Safety Study of MK-5172 + MK-8742 in the Treatment of Chronic Hepatitis C Virus in Participants Who Are Co-Infected With Human Immunodeficiency Virus (C-EDGE COINFECTION) (MK-5172-061).

ClinicalTrials.gov Identifier: NCT02105662

An Efficacy and Safety Study of MK-5172 + MK-8742 in the Treatment of Chronic Hepatitis C Virus Genotype 1, 4, 5 or 6 Infection in Treatment-Naïve Participants Who Are on Opiate Substitution Therapy (C-EDGE RECOVERY)(MK-5172-062).

ClinicalTrials.gov Identifier: NCT02105688

Study of Efficacy and Safety of MK-5172/MK-8742 Combination Regimen for Treatment-Naïve Participants With Chronic Hepatitis C Virus Genotypes 1, 4, 5, and 6 (MK-5172-060). ClinicalTrials.gov Identifier: NCT02105467

24 APR 2015: Merck announced the first presentations of data from the company's ongoing C-EDGE pivotal Phase 3 clinical trial program evaluating the investigational once-daily tablet grazoprevir/elbasvir (100mg/50mg) in patients with or without cirrhosis who are infected with chronic hepatitis C virus (HCV) genotypes 1, 4 or 6 (GT1, 4 or 6). Patients in both the HCV infected, treatment-naïve (C-EDGE TN), and HIV/HCV co-infected, treatment-naïve (C-EDGE CO-INFXN) trials treated for 12 weeks achieved rates of sustained virologic response 12 weeks after the completion of treatment (SVR12) of 95 percent (299/316 and 207/218, respectively). In addition, HCV infected, treatment-experienced patients (C-EDGE TE) treated with or without ribavirin (RBV) for 12 weeks achieved SVR12 rates of 94 percent (98/104) and 92 percent (97/105), respectively, and those treated for 16 weeks achieved SVR12 rates of 97 percent (103/106) and 92 percent (97/105), respectively.

23 APR 2015: Merck announced the first presentation of data from C-SURFER, the company's Phase 2/3 clinical trial evaluating grazoprevir (100mg) and elbasvir (50mg) in patients with advanced chronic kidney disease (CKD) infected with chronic hepatitis C virus (HCV) genotype 1 (GT1). Following 12 weeks of treatment with grazoprevir and elbasvir, 99 percent (115/116) of patients in the pre-specified primary population for analysis of efficacy data achieved a sustained virologic response 12 weeks after the completion of treatment (SVR12).

08 APR 2015: Merck disclosed that primary results from the C-EDGE program, Phase 3 clinical trials evaluating grazoprevir/elbasvir (with and without ribavirin) across multiple HCV genotypes (1, 4 and 6) and diverse patient populations, including those difficult to treat, over a 12-week treatment duration will be presented at International Liver Congress 2015 on 24 - 25 April 2015.

11 NOV 2014: Merck disclosed that grazoprevir/elbasvir registration studies within the C-EDGE program – including C-EDGE TN (treatment-naïve), C-EDGE CO-INFXN (HIV/HCV co-infected) and C-EDGE TE (treatment-experienced) -- are now fully enrolled. Results from these trials are anticipated in the first half of 2015.

11 APR 2014: Merck announced that the company has initiated Phase 3 clinical trials for MK-5172/MK-8742. The Phase 3 program, called C-EDGE, will evaluate the safety and efficacy of MK-5172/MK-8742 with and without ribavirin in various genotypes and across a broad range of patient populations with chronic HCV. Study cohorts will include: C-EDGE TN (GT1, GT4-6; treatment-naive ± cirrhosis), C-EDGE CO-INFXN (GT1, GT4-6; treatment-naive ± cirrhosis with HIV/HCV co-infection), C-EDGE RECOVERY (GT1, GT4-6; treatment-naive ± cirrhosis; ± HIV/HCV co-infection on opiate substitution therapy), and C-EDGE TE (GT1, GT4-6; prior failed treatment with peginterferon/ribavirin; ± HIV/HCV co-infection).

28 H2 2015: Expect Phase III trial results. Source: Mylan Press Release (26 JAN 2015).

Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks in Adults With Chronic HCV Infection (ASTRAL-1). ClinicalTrials.gov Identifier: NCT02201940

Comparison of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 12 Weeks in Adults With Chronic Genotype 2 HCV Infection (ASTRAL-2). ClinicalTrials.gov Identifier: NCT02220998

Comparison of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 24 Weeks in Adults With Chronic Genotype 3 HCV Infection (ASTRAL-3). ClinicalTrials.gov Identifier: NCT02201953

26 JAN 2015: Mylan disclosed that Phase 3 studies evaluating the combination of GS-5816 and sofosbuvir are currently underway, with data anticipated in the second half of 2015.

29 2016: Expect US filing. Source: Roche Website (15 APR 2014).

15 APR 2014: Roche expects to file application for approval in US by 2016.

21 JUL 2011: Company expect US Filing for Danoprevir for Hepatitis C in 2014.

30 2016: Expect European filing. Source: Roche Website (15 APR 2014).

15 APR 2014: Roche expects to file application for approval in EU by 2016.

21 JUL 2011: Company expect EU Filing for Danoprevir for Hepatitis C in 2014.

31 Q4 2014: Estimated Study Completion Date.

NOV 2012: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (03 AUG 2011).

Safety and Efficacy of ANA598 Administered With Pegylated Interferon and Ribavirin in Genotype-1 Patients With Chronic HCV Infection. ClinicalTrials.gov Identifier: NCT01281423

16 OCT 2014: Roche disclosed in its pipeline that RG7790 for Hepatitis C in Phase II development.

31 MAR 2014: Roche disclosed RG7790 for Hepatitis C in Phase II development.

13 OCT 2011: Anadys Pharmaceuticals released interim antiviral response and safety data from an ongoing Phase IIb study of setrobuvir in combination with pegylated interferon and ribavirin (P/R) in genotype 1 hepatitis C patients. Setrobuvir is the Company's direct-acting antiviral being developed for the treatment of chronic hepatitis C, or HCV. The primary endpoint of the study is Sustained Virological Response 24 weeks after patients conclude all treatment, known as SVR24. In addition to the interim data released today, data through 24 weeks of dosing are expected around year-end. The study is being conducted at sites in the United States, Canada, Australia and New Zealand.

32 JUN 2015: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (03 JAN 2012).

A Study to Treat Subjects With Telaprevir, Ribavirin, and Peginterferon Who Are Coinfected With HIV and Hepatitis C Virus (HCV). ClinicalTrials.gov Identifier: NCT01467479

08 JAN 2012: Phase 3 study in people co-infected with hepatitis C and HIV: Enrollment is ongoing in a Phase 3 trial of INCIVEK combination therapy in people co-infected with genotype 1 hepatitis C virus and HIV.

33 JAN 2015: Estimated Study Completion Date.

AUG 2014: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (17 OCT 2013).

Miravirsen in Combination With Telaprevir and Ribavirin in Null Responder to Pegylated-Interferon Alpha Plus Ribavirin Subjects With Chronic Hepatitis C Virus Infection. ClinicalTrials.gov Identifier: NCT01872936

27 AUG 2013: Santaris Pharma announced the completion of enrollment of its Phase 2 miravirsen 12-week monotherapy study of miravirsen, a host-targeted, pan-HCV genotype antiviral agent, in subjects who were "null responders" to pegylated interferon alpha and ribavirin (peg-IFNα/RBV). The company also announced the enrollment of the first patient into another Phase 2 study of miravirsen in combination with telaprevir and ribavirin, also in null responders to peg-IFNα/RBV.

34 Q2 2015: Expect Phase II trial initiation. Source: Regulus Therapeutics Press Release (09 FEB 2015).

09 FEB 2015: Regulus disclosed that it expects to file both a Clinical Trial Application and an Investigational New Drug application for RG-101 with the goal to initiate studies in Europe and the United States in the second quarter of 2015.

35 SEP 2015: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (24 JUL 2014).

Safety and Efficacy Study of Single Doses of TT-034 in Patients With Chronic Hepatitis C. ClinicalTrials.gov Identifier: NCT01899092

29 APR 2015: Benitec Biopharma announced that the fifth patient in the company's 'first in man', Phase I/IIa dose escalation clinical trial of TT-034 for hepatitis C virus (HCV) infection, has been dosed at the Duke Clinical Research Unit. The fifth patient is the third and final patient to be dosed in Cohort 2. Benitec has now initiated a third site, the Texas Liver Institute in San Antonio, Texas, and they have started to pre-screen patients for the TT-034 trial. Following completion of the first two patient cohorts and initiation of a third trial site, Benitec will now move to conventional clinical trial reporting for cohorts 3 through to 5 of the dose escalation study.

07 APR 2015: Benitec Biopharma announced that laboratory results from liver biopsies in the company's 'first in man', Phase I/IIa clinical trial of TT-034 for hepatitis C confirmed that the trial is proceeding according to expectations. The expression of the three shRNAs in patients' liver cells is an essential requirement for TT-034 to exert a clinical reduction of hepatitis C viral load. The most recent assay of the biopsies confirmed this expression occurred in all three patients dosed to date. These results were obtained from the biopsies of the first two patients in cohort 1 and the first patient in cohort 2. The second patient in cohort 2 has not yet been biopsied, and the third patient in cohort 2 is yet to be dosed due to a personal issue. In cohorts 1 and 2, the dose of TT-034 is sub-therapeutic and, therefore, the amount of shRNA produced will not result in reduction of hepatitis C viral load.

11 MAR 2015: Benitec announced that the fourth patient in the company's Phase I/IIa dose escalation clinical trial of its lead program TT-034 for treating hepatitis C was dosed at the Duke Clinical Research Unit. This is the second patient to be dosed in Cohort Two, with the third and final patient in Cohort Two well advanced in their preparation for dosing.

07 JAN 2015: Benitec announced that the third patient in its Phase I/IIa clinical trial of TT-034 for hepatitis C was dosed at the Duke Clinical Research Unit (USA). This is a significant step for this "first in man" study, and follows review of the collective data from the first two patients by the independent Data Safety Monitoring Board (DSMB). The DSMB determined that the patients from the first dosing cohort were clear of any significant treatment-related adverse events. The newly dosed

patient will be monitored for six weeks and results will be reviewed by the DSMB. Should the results indicate appropriate safety outcomes, the DSMB is expected to recommend that the remaining two patients in the second cohort be dosed.

36 Q2 2015: Expect Phase II trial initiation. Source: Regulus Therapeutics Press Release (09 FEB 2015).

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40 Q2 2015: Expect Phase II trial initiation. Source: Regulus Therapeutics Press Release (09 FEB 2015).

09 FEB 2015: Regulus disclosed that it expects to file both a Clinical Trial Application and an Investigational New Drug application for RG-101 with the goal to initiate studies in Europe and the United States in the second quarter of 2015.

41 SEP 2015: Estimated Primary Completion Date (Final data collection date for primary outcome measure). Source: ClinicalTrials.gov (17 DEC 2014).

Pegylated Interferon Alpha-2b Versus Hydroxyurea in Polycythemia Vera (PROUD-PV). ClinicalTrials.gov Identifier: NCT01949805

11 MAR 2015: PharmaEssentia and AOP Orphan announced completion of recruitment of the pivotal European Phase III trial PROUD-PV to support global marketing of P1101 (Ropeginterferon alfa-2b). US FDA has agreed that the data from this trial can be used for the BLA filing in the US.

05 MAR 2015: AOP Orphan Pharmaceuticals announced the completion of recruitment for its phase III trial PROUD-PV to support global licensure of Ropeginterferon alfa 2b (AOP2014/P1101). Design and endpoints of this trial have been discussed and agreed with both the European Medicines Agency EMA and the U.S. FDA, to support global licensure of Ropeginterferon alfa 2b, which also has Orphan Drug status in both Europe and the USA. Since its commencement in October 2013 over 260 PV patients have been recruited in 50 centers all across Europe. Enrollment of patients has been successfully completed in February 2015.

42 Q2 2015: Expect Phase II trial initiation. Source: Regulus Therapeutics Press Release (09 FEB 2015).

09 FEB 2015: Regulus disclosed that it expects to file both a Clinical Trial Application and an Investigational New Drug application for RG-101 with the goal to initiate studies in Europe and the United States in the second quarter of 2015.

43 2015: Expect Phase IIb trial results. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014).

A Study to Evaluate the Safety and Antiviral Effect of Multiple Doses of ABT-493 and ABT-530 in Adults With Genotype 1 Hepatitis C Virus (HCV). ClinicalTrials.gov Identifier: NCT01995071

10 SEP 2014: Enanta Pharmaceuticals announced that AbbVie, Enanta's development partner for protease inhibitors for hepatitis C virus (HCV), has initiated a phase 2b clinical study with ABT-493, Enanta's next-generation protease inhibitor.

The phase 2b study being conducted by AbbVie will evaluate the safety and efficacy of ABT-493 co-administered with ABT-530, AbbVie's next generation NS5A inhibitor, in HCV patients. AbbVie has informed Enanta that results from this trial are expected in 2015.

44 2015: Expect Phase III trial initiation. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014).

10 SEP 2014: AbbVie plans to start phase 3 development of ABT-493 in combination with ABT-530 next year.

45 2015: Expect Phase IIb trial results. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014).

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46 2015: Expect Phase III trial initiation. Source: Enanta Pharmaceuticals Press Release (10 SEP 2014).

10 SEP 2014: AbbVie plans to start phase 3 development of ABT-493 in combination with ABT-530 next year.

47 Estimated PDUFA Date: 01 OCT 2015.

Review Type: 6 Months (Confirmed). Source: Enanta Pharmaceuticals Press Release (23 APR 2015).

23 APR 2015: Enanta Pharmaceuticals announced that AbbVie has stated that the U.S. FDA has accepted AbbVie's NDA and granted priority review for its all-oral, interferon-free, two direct-acting antiviral (2-DAA) treatment regimen consisting of the fixed-dose combination of ombitasvir, paritaprevir, ritonavir (OBV/PTV/r), with ribavirin (RBV) for the treatment of adult patients with chronic genotype 4 (GT4) hepatitis C virus (HCV) infection.

05 MAR 2015: AbbVie disclosed in its presentation that 2-DAA has been filed in U.S.

48 H2 2015: Expect Japanese regulatory decision. Source: Enanta Pharmaceuticals Press Release (12 FEB 2015).

16 APR 2015: AbbVie announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted priority review for its investigational, two direct-acting antiviral treatment of ombitasvir/paritaprevir/ritonavir. This all-oral treatment is interferon (IFN) and ribavirin (RBV)-free and will be dosed once daily.

12 FEB 2015: Enanta Pharmaceuticals announced that AbbVie has submitted an NDA to the Japanese Ministry of Health, Labour and Welfare (MHLW) seeking approval for AbbVie's investigational, once-daily dosed, all-oral, ribavirin (RBV)-free and interferon (IFN)-free, 12-week, two direct-acting antiviral treatment consisting of ombitasvir/paritaprevir/ritonavir

(OBV/PTV/r). The submission is for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection. AbbVie has previously announced that they expect regulatory approval in Japan in the second half of 2015.

49 2015: Expect Phase III trial initiation. Source: Merck & Co Interim Results (04 FEB 2015).

04 FEB 2015: Merck & Co disclosed that it has started the Phase 2 C-CRESTstudies to study combination regimens of grazoprevir and MK-3682 (formerly IDX21437) with either elbasvir or MK-8408 for the treatment of HCV infection. The company expects to begin Phase 3 studies in 2015.

50 MAY - AUG 2014: Expect Phase II trial initiation. Source: Idenix Pharmaceuticals Press Release (07 APR 2014).

07 APR 2014: Idenix Pharmaceuticals expects to initiate a combination clinical trial of IDX21437 and samatasvir, a pan-genotypic NS5A inhibitor, in mid-2014.

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